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Critical Risk Assessment and Management in Pharmaceutical Industry

Abida Zameer
Harrisburg University of Science and Technology

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Abstract

Background

Proper implementation of principles of project risk management is well known to minimize the impact of threats to any project. However, the determination of critical success factors which threat the success of pharmaceutical projects at baseline are usually uncertain.

Methods

Data was collected using self-administered structured questionnaire generated solely for the purpose of the current research. The questionnaire was administered via e-mail to professionals employed in the pharmaceutical industry located in Boston area using www.surveymonkey.com. The introduction and purpose of the questionnaire was described in the message accompanying the questionnaire.

Results:

Out of the 14 critical success factors listed in the questionnaire , respondents ranked good communication on the top with weighted average (2.00) followed by Clear communication/ feedback (1.92) and Organizational adaptation/ culture/ structure (1.92).

Conclusion

Good leadership and clear communication and organization culture were determined to be the most important critical success factors for implementation of risk assessment management practices.

Key words: Risk Management, Project Management, critical success factors, pharmaceutical

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1.Introduction

Pharmaceutical landscape is in a constant change as markets are growing and merging with big companies. In order to be in lead and to gain a competitive advantage these companies needs to be more specialized and flexible. Therefore, the importance of project management especially the risk management in new product development cannot be ignored to bring a successful product to the market.

Results of multiple studies have shown “the industries declining productivity challenges, the change in commercial models, and the growth of emerging markets” (Gautam, A.2016). To deal with the challenges, change, and competition it is important that the industry should focus more on the research and development to gain a competitive advantage in the market by launching a new product.

As we know that the research and development activities are quite risky, so it is necessary to adopt risk management tools to manage research and development projects. The critical aspects of successful project management are Risk identification, quantification, and mitigation of the risks (Mastroianni, A. 2011).

Management of risk is a structured approach which is used for “identification, assessment, and prioritization of risks followed by planning of resources to minimize, monitor, and control the probability and impact of undesirable events” (Wang, J. et.al 2010) The “effective risk management enables proactive management” gives the motivation for developing such a structured risk management process”.

The structured risk management is applied in areas like management, politics, Construction, finance, etc. In R& D (Research and development) projects the literature suggests

that it is more focused on individual project level that limits the ways to identify, assess and prioritize risks within a single project scope (Wang, J. Lin, W. & Huang, Y. 2010).

It is doable to deal with the problems before they get materialized and to minimize their impact on progress or outcome of the project. However, to achieve the full potential of risk management it's important to check that the process matches the organizational context and the requirements of the industry. Also, effective tools should be developed that aligns with the process and help in the proper implementation of Risk Assessment and Management Practices.

2. Problem statement and Justification

The Pharmaceutical landscape is constant change as markets are growing and merging with big companies. To be in the lead and to gain a competitive advantage, these companies need to be more specialized and flexible. Therefore, the importance of project management especially the risk management in pharmaceutical space cannot be ignored to bring a successful product to the market.

Forecasting the risks during the project planning phase continues to be a challenge as for projects are yet to be executed in future. This problem is exacerbated especially for complex projects with long life cycles and multiple dependencies, as is characteristic of drug development programs.

The risks becomes more visible towards the end of the project when all mandatory projects related documentation is to be submitted to global regulatory authorities, for review and to get approval for marketing. Counterintuitively, arranging the documentation as per the requirements of the regulatory bodies remains an isolated process, accomplished after the completion of studies.

Compiling electronic Trial Master File (eTMF) is a commonly used practice in the Biopharmaceutical industry with the objective of making the review and filing process less cumbersome, hence easier and faster.

However, most of the submissions still miss the submission deadlines due to a lack of effective risk assessment and management techniques implemented during the project. This lead to further exploration into the potential issues that are hindering the proper implementation of risk assessment and management practices in a pharmaceutical company.

As we know that the effective risk management process leads to the proactive project management that's what gave the motivation to conduct this study. The main objective of this thesis is

1. To find the top three critical success factors for risk assessment and management practices in a pharmaceutical industry
2. To find out the most important risk in the pharmaceutical industry

The main hypothesis of this project is:

- Good leadership and clear communication and organization culture are the most important critical success factors for the implementation of risk assessment and management practices in the pharmaceutical industry.
- Regulatory risk is the most important risk in the pharmaceutical industry.

3.Literature Review

3.1 Risk Management Overview

There is limited literature related to project risk management in a bio-pharmaceutical industry because the project risk management is not commonly practiced in this industry. Sometimes companies fear that projects would be halted/paralyzed by making the analysis of risks, or even identifying the risks will have a negative impact on the project. The importance of risk management has been realized in the recent years and risk has been categorized in R&D projects one such illustration was given by Pass and Postle (2002), Fig 1

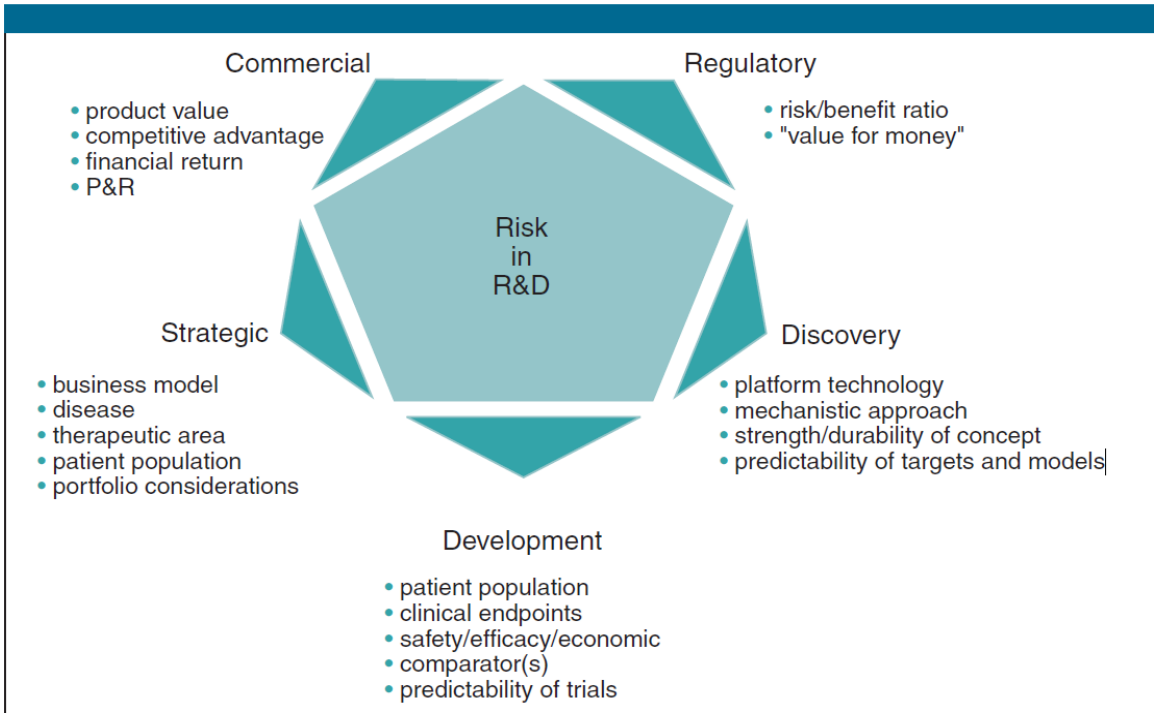

Fig 1. Risks posed by pharmaceutical R & D by Pass and Postle (2002). Unlocking the Value of R&D, Managing the Risks. *BioPharm.* Retrieved on May 7, 2017 from http://images.alfresco.advanstar.com/alfresco_images/pharma/2014/08/22/ca6f34ad-7972-4f9c-9c3d-258d66b4e67b/article-22988.pdf

Data suggests that the “business decisions relating to product development are complex and difficult due to the high capital investment and low probability of success of development projects”(Choi *et al.*2010). Based on this Mastroeni (2011) has started his literature review by discussing the project failure rate because the projects do not start on time. Mastroeni (2011) categorized the risks into technical risks, project management risks, organization and external risks.

Managing R & D uncertainly to improve the project success rates has been studies for many years, and the risk management is one of the approaches that have been widely used in practice (Smith and Merritt 2002). Results of several studies have shown that applying the risk management techniques can improve the success rate (Wang, J., Lin, W. & Huang, Y. 2010).

Due to the long development lead-time, increasing cost and high failure rates for the drug development. It’s important to effectively manage the risks in a pharmaceutical company. Most of the pharmaceutical risk management is usually focused on Pharmacovigilance/Drug Safety issues including but not limited to detection, signaling and remediation and understanding the adverse effects of medicines (Wang, J., Lin, W. & Huang, Y. 2010).

Some of the studies on pharmaceutical risk management like Saari (2004) used the project risk management approach to the drug development. Others have developed pipeline or portfolio management approaches to select the projects.

There is a shortage of research that provides an integrated approach to align or link “operational risk management with corporate strategies” and to provide a systemic approach for identification, assessment, planning and control of the risks (Wang, J., Lin, W. & Huang, Y. 2010).

Several researchers have developed methodologies and classifications to improve the success rate of the projects.

Ahn *et al.* 2008 classified the risks into the following:

> Risk factors within product development can be classified into nine categories: (1) human resources, (2) management/senior leadership support, (3) business or organizational impacts, (4) technology, (5) vendor, (6) scope, (7) schedule, (8) budget, and (9) project linkages. NPD project managers are challenged with the task of acquiring knowledge and managing sources of uncertainty to reduce the risk of failure.

Mastroianni (2011) also believe in the classification of the risks factors within product development and whether the risks are interdependent or dependent and whether there should be a standardize risk management methodology.

The risks in drug development projects depend on the phase of drug development. For example in Phase I the odds of completing the project is way too higher than in the later phase because in Phase I of the trial the subjects are healthy as compared to Phase III.

As stated earlier in that the risk management in the field of pharmaceutical drug development projects is very scarce, Reynolds in 1998 stated that pharmaceutical industry should learn from the other industries about three things. Firstly, about the variance that could be raised from any level into the project team and team member should be empowered to release it. Secondly, the use of risk register should be utilized to figure out the future costs, actions, and variance. Special action teams could be hired to manage off-line activities like management of the risks. Finally, risks should be on the weekly meeting topics lists (Reynolds 1998).

Young Hoon and Collen K (2008) stated in their paper that there are 13 best practices that can be applied to the R& D projects in order to improve risk management and the uncertainties related to project management. It has been suggested that the risk management implementation in the area of pharmaceutical drug development projects may require more focus on adaptation to the specific needs and the project challenges (Young Hoon, K. & Colleen K., D.2008).

In the drug development project risk management should be planned just like any other project activity. By doing this it will bring more structure to the process and it will be easier to follow plans.

3.2 Risks

It is important to understand the meaning of the term “risk” must clearly so that project risks can be effectively managed. In the context of a project, the most concerning thing is about its potential impacts on project objectives that include cost and time. A general definition of “risk” in this context is:

“Risk is an uncertainty that matters; it can affect project objectives negatively or positively” according to Risk Management Task Group, 2012)

According to SBP 2003 “Risks are usually defined by the adverse impact on profitability of several distinct sources of uncertainty. While the types and degree of risks an organization may be exposed to depend upon a number of factors such as its size, complexity business activities, volume, etc.” (Muller, R.2009)

Risk can be further classified into two types

- Systematic risks
- Unsystematic risks

Systemic risks are those risks that are inherent to entire market or system. It often called as market risks or sometimes referred to as volatility. Systematic risks cannot be avoided.

Unsystematic risks are those risks associated with individual assets. Such type of risks can be avoided. Unsystematic risks are also called a specific risk.

According to PMBOK risks can be classified as technical, external, organizational and Project management risks.

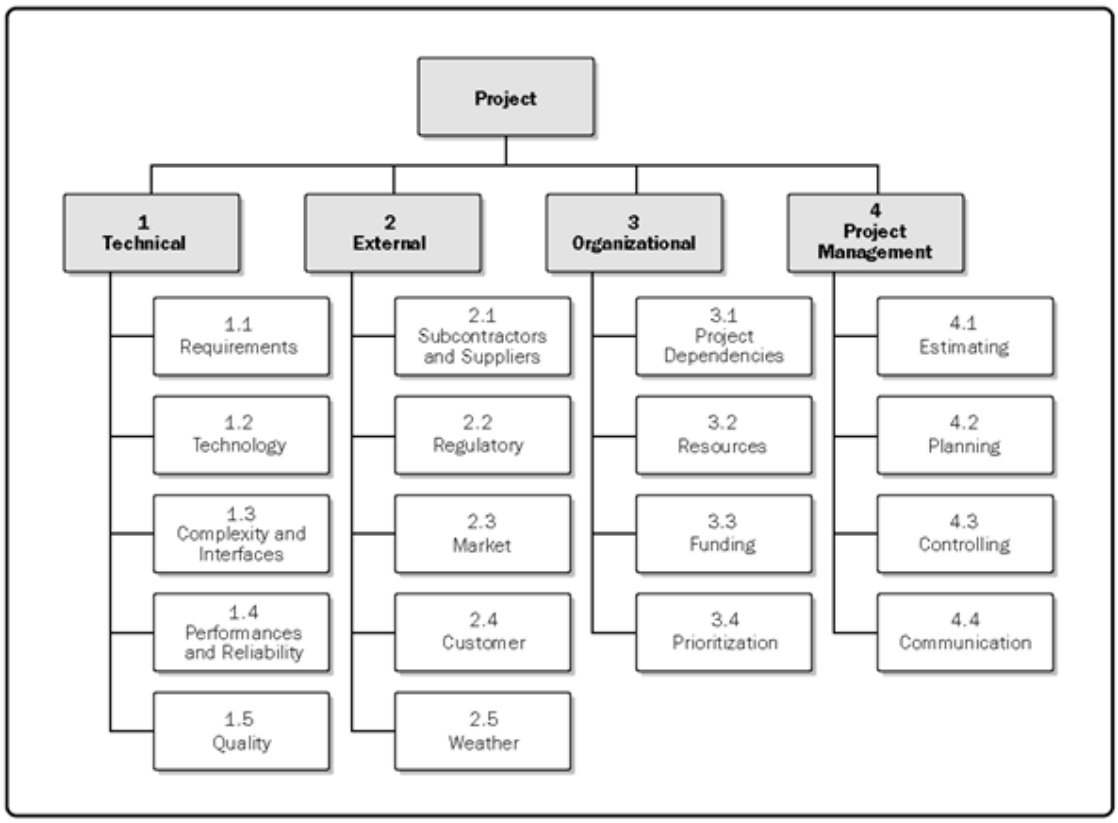

Fig 2. Risk Breakdown Structure taken from PMBOK

Per KPMG 2009 global survey findings it is found that the pharmaceutical Risk management is considered as a C level issue with the shortage of experts in the industry who can handle risks and they usually spend most of their time in controlling regulatory risks which they

think is the biggest threat to the company. Here is the chart showing the risks that poses threat to company's global business.

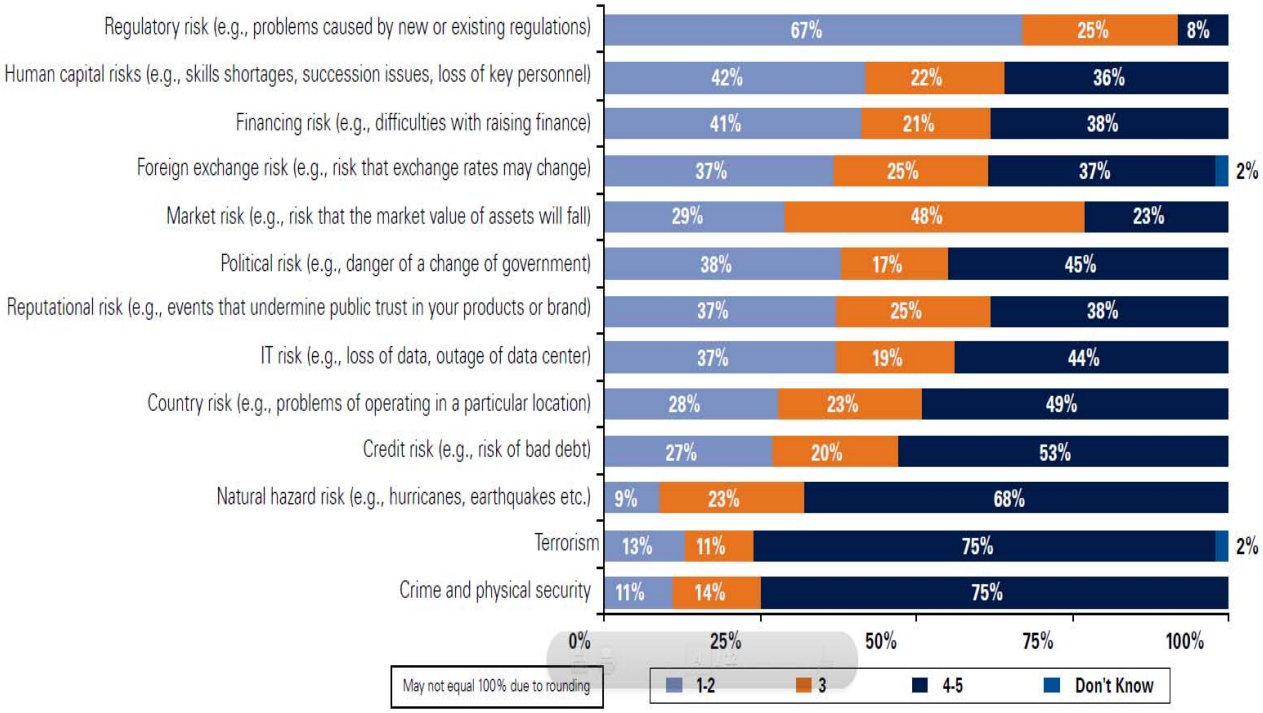

Fig 3. Risks Posing Threat To Company's Global Business Operations

Risk Management in pharmaceutical and Life Science Industry, An economist Intelligence Unit Retrieved form https://www.eiuperspectives.economist.com/sites/default/files/Risk%20management%20in%20the%20pharmaceuticals%20and%20life%20sciences%20industry.pdf

It has been found that the role of risk management in pharmaceutical is not that advance and the main focus of the industry are to focus on the regulatory compliance. In the survey it has been indicated that the regulatory risk is the most important risk in the pharmaceutical industry.

Table 1.Risks ranking in pharmaceutical company

Regulatory risk is No.1 for all pharmaceuticals and life sciences companies, but other risks vary by company size				
How significant a threat do the following risks pose to your company's global business operation today? (Companies ranked by annual revenue) *(Percent of respondents who selected 1 or 2 on a 5-point scale, where 1=very high risk and 5=very low risk)*				
Risk	**All companies**	**$500m or less**	**$500m to $5bn**	**$5bn or more**
Regulatory risk (e.g., problems caused by new or existing regulations)	67%	70%	68%	64%
Human capital risks (e.g., skills shortages, succession issues, loss of key personnel)	42%	45%	36%	46%
Financing risk	41%	70%	43%	14%
Political risk (e.g., danger of a change of government)	39%	35%	36%	41%
Reputational risk (e.g., events that undermine public trust in your products or brand)	37%	52%	9%	50%
Foreign exchange risk (e.g., risk that exchange rates may change)	37%	33%	23%	55%
IT risk (e.g., loss of data, outage of data center)	37%	30 %	41%	36%
Market risk (e.g., risk that the market value of assets will fall)	29%	24%	41%	23%
Country risk (e.g., problems of operating in a particular location)	28%	38%	18%	27%
Credit risk (e.g., risk of bad debt)	27%	25%	36%	18%
Terrorism	13%	15%	5%	18%
Crime and physical security	11%	10%	9%	14%
Natural hazard risk (e.g., hurricanes, earthquakes, etc.)	9%	10%	9%	9%

Risk Management in pharmaceutical and Life Science Industry, An economist Intelligence Unit Retrieved form https://www.eiuperspectives.economist.com/sites/default/files/Risk%20management%20in%20the%20pharmaceuticals%20and%20life%20sciences%20industry.pdf

3.3 Risk Management

Risk Management is defined in different ways. According to Anderson and Terp (2006), it's a process that can be used in eliminating. Reducing and controlling risk and enhancing benefits. The aim of the risk management is to maximize the benefits by reducing the risks.

According to the Project Management Institute's PMBOK, Risk management is one of the ten knowledge areas in which a project manager must be competent. Project risk is defined by PMI as, "an uncertain event or condition that, if it occurs, has a positive or negative effect on a project's objective such as time, cost scope and quality." (Wikipedia, 2017)

So by any definition, the risk is nebulous and because of this nature, it is sometimes difficult to manage the risk effectively. There are certain ways that can be used to effectively manage the risks these are as follows:

1) There should be an implementation of a defined process
2) Risks must be identified.
3) Objective measures to be used to quantify risks
4) Risks can be prioritized based on impact and probability
5) Developing a mitigating strategy
6) Monitoring a mitigating strategies
7) Development of reusable risk models

8) Providing oversight in order to make sure compliance
9) Implementing an active feedback loop

3.3.1 Risk Identification

Risk identification is a disciplined process that involves using checklists of the risks. It is considered as the first step of the risk management. The main objective of risk identification is to identify the risks that can impact the project ability to achieved progress. This risk can be internal or external. Sometimes the risks can be identified using the experience or lessons learned.

3.3.2 Risk evaluation

Once the risk has been identified, the next step is to evaluate the risks on the probability that the event may occur and what could be the loss due to this event. All the risks are not same; some risks have the chances of occurrence and its severity greater than others.

So the criteria of determining high impact risks can be beneficial in narrowing down the focus on a handful of critical risks. Risk evaluation in a broad sense is the development of understanding about the potential risks that have a greater chance of occurring and can severely impact the project.

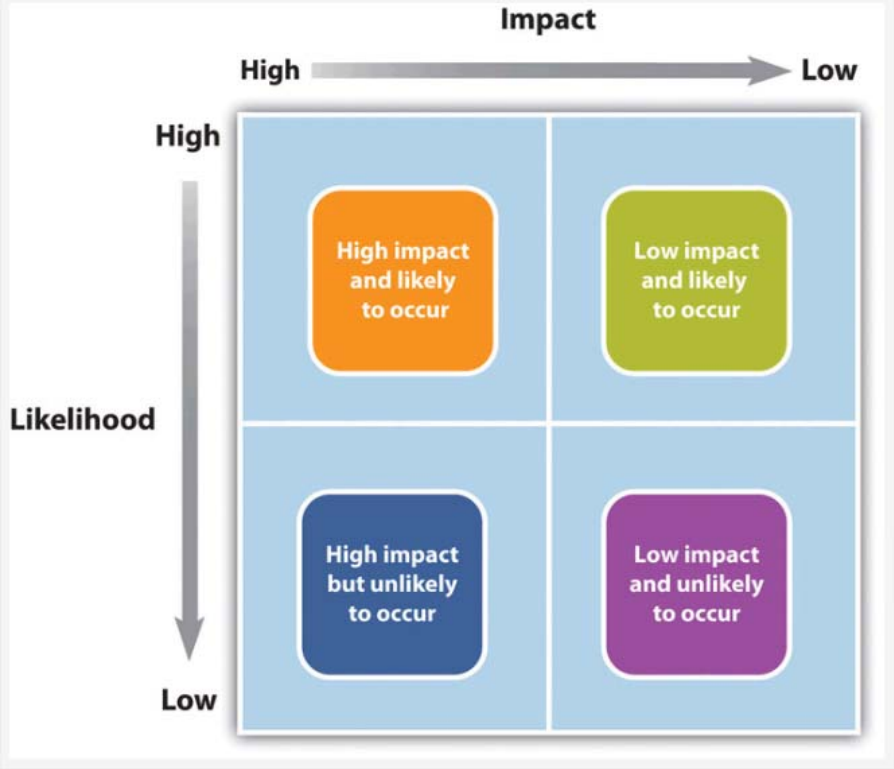

Fig 4 Risk and Impact taken from https://pm4id.org/chapter/11-2-risk-management-process/

The above fig indicates that there is a ***positive correlation*** between project risk and project complexity. For example a project with a new technology will have a high risks because of complex nature of the project.

3.3.3 Risk Mitigation

Once the risk has been identified and the evaluation is for the type of risks, the project team develops a mitigation plan to mitigate the risks. That can be done in the following ways

- Avoiding the risks
- Sharing the risks
- Reducing the risks
- Transferring the risks

These risks mitigating techniques can be helpful in reducing the individual risks of the project. The risk mitigation plan covers all the information related to the approach taken to identify the risks and the actions taken to reduce the risks.

3.3.4 Monitoring and Review

It is an integral step used for risk management process. Risks should be monitored to make sure that any change in environment does not affect or alter the risk priorities. The risk monitoring should be done on an annual basis. (Prapawadee N, R (2009)

The risk management process is cyclical in nature hence it should be made an integral part of management to successfully run the projects.

3.4 Critical success factors of risk assessment and management practices.

3.4.1 Overview

The definition of critical success factors was introduced by Rochart in 1979. According to Rochart (1979), critical Success Factors are “The limited number of areas in which Results, if they are satisfactory, will ensure successful competitive performance for the Organization. They are the few key areas where things must go right for the business to flourish. If results in these areas are not adequate, the organization’s efforts for the periods will be less than desired”.

According to other researchers like Boynton (1984) Critical Success factors are something that are helpful the success of an organization, for example, they help in maintaining a high performance of an organization’s existing and future operating activities.

Freund (1988) has a notion that that Critical Success factors are very important for the health of overall organizational objectives, mission, and strategies. He suggested that it is difficult to focus on a large number of critical success factors so it is important for an organization to have only five to ten critical success factors.

There are many contributions and papers on Critical success factors emphasizing the role of critical success factors in risk management. Different authors have different opinions on the number and type of critical success factors for example Grabowski and Roberts (1999) believes that there should be fours factors i.e. Organizational Structuring and Design, Communication, Culture and trust. While Galorath (2006) argues that there should be five factors, i.e., Top-level management support, management structure and processes, team work, culture, Metrix. Hnasali (20020 believes that the Leadership, culture, structure, Information technology and Metrix should constitute as critical success factors.

So there were different sets were presented by different authors as shown below:

Table 2 Comparison of different views on critical success factors

Critical Success Factor	**Grabowski and Roberts (1999)**	**Daniel Galorath(2006)**	**Anthony Carey(2001)**	**Farida Hasanali(2002)**
1 Commitment and Support from top management		Top-level management support		Leadership
2 Communication	Communication		Verifying your judgments	

3 Culture	Organizational Culture			Culture
4 Organizational Structure	Organizational Structuring and Design		Change management	Structure, roles, and responsibilities
5 Training			Embedding risks developing of risk training course	
6 Information Technology				Information technology infrastructure
7 Trust	Trust			
8 others		Acknowledgment that risk is reality	The importance of sound judgment	Measurement
		Commitment to identify and manage risks	Identification issues	
			Keep control of your reputation	

			Assessing the importance of risks	
			Remuneration issues	

Table is taken from Prapawadee N, R (2009) Critical Success Factors for effective risk management procedures in financial industries Retrieved from https://pdfs.semanticscholar.org/f97a/7667bab74756fc9b26f594f0ae7f9a4c1bb2.pdf

The table above reflects the complete model of risk management used by different authors. So based on the table the author has used 14 critical success factors used in pharmaceutical industry these are:

Table 3 Critical Success Factors

Critical Success Factors for Risk Management
Support from senior management
Clear and realistic objectives
Good communication/ feedback
Skilled/ suitably qualified/ sufficient staff/team
Competent Project manager
Sufficient /well allocated resources
Good leadership
Proven/ familiar technology

Realistic schedule
Risks addressed/ assessed/ managed
Effective monitoring/ control
Adequate budget
Organizational adaptation/ culture/ structure
Training provision

3.4.2 Support from senior management:

There are multiple studies conducted on this factor and the results from these studies have found that it very important to have support form senior management because their supports have a direct impact on the organizational success Ifinedo (2008).

One study indicates that senior management support or top management support should be considered as the critical success factor because they are the ones that support a wide range of activities of a project like project initiation activities, developing procedures of a project, running training programs, help in establishing a project management office and supporting quality management Zwikael (2008).

Some believe that top management support is beneficial for managing risks by improving the decision making process. It is considered that successful risks mitigations is directly dependent on the support from senior or upper management

So in order to have the risk mitigated and addressed it is important to have support from the top management as they play a key role in influencing the success of a project in an organization Prapawadee N, R (2009).

3.4.3. Good communication/ feedback:

Good communication is an important tool for almost every organization as there are many people working altogether in the same roof; they may have different opinions and discussion so those opinions can result in different conclusions. The key to good communication is that the message is clear and delivered across the team.

Communication is considered as an important skill for leaders and top-level management because it is helpful in setting clear mutual expectations, objectives and goals. It is also helpful in ensuring that the team members understand and support all the team related activities and their future goals (Clutterbuck and Hirst, 2002).

According to Finniston (1975) gathering, storing and delivering and communicating information is helpful in growing business. Communication is an important tool for making sure that all the employees know about the activities happening outside or inside of their organization. Grabowski and Roberts (1999) believe that the communication in risk mitigation cannot be ignored as it provides opportunities to the team about the happenings and their impact.

For successful risk management it is important to have a proper and effective division of responsibilities in a multilayered industry like pharmaceutical industry. The management and handling of certain types of risks should be defined clearly and they should be communicated to the project team and the whole organization.

It is important to make sure that communication is maintained within and between these layers. The figure below shows the Issues to be considered in organizing and implementing drug development risk management and communication is one of them.

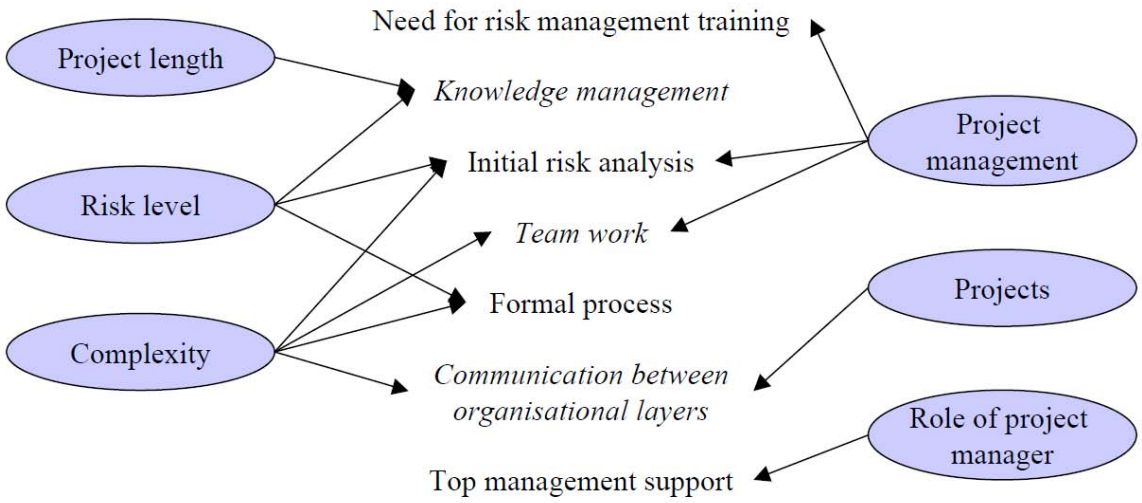

Fig 5 Risk Mitigation Strategies

3.4.4 Organizational Culture

The word culture came from Latin word culture stemming from colere, which means “to cultivate". The word culture is used in three basic senses.

1. Excellence of taste in the fine arts and humanities, also known as high culture

2. An integrated pattern of human knowledge, belief, and behavior that depends upon the Capacity for symbolic thought and social learning

3. The set of shared attitudes, values, goals, and practices that characterizes an institution, Organization or group (Beardsell J, 2009).

According to Mosadeghrad 2006 management success is highly dependent on Organizational culture. The corporate and collaborative organizational culture is always welcome by the team and Management.

The risk management needs the combination of several cultures which could be helpful in making a system cohesive and friendlier. In order for the management to succeed it is important conduct meeting, share beliefs and seek consensus (Grabowski and Roberts, 1999).

Culture is important in risk management because transferring the knowledge requires interaction among individuals or team, exchanging ideas and knowledge sharing with each other.

3.3.5. Training

Training is becoming an integral part of the organization. Almost all companies provide training to the employees at some point of time. They can be conducted on the job or off the job which is conducted outside. These trainings usually cover power points. Films, case studies, simulation etc.

These trainings success is influenced by the training manual, mentorship programmes, interactive learning, and problem based learning strategies, support from the staff etc (Moss, 1997) which can be utilized to equip the team with necessary information on how to handle and mitigate a risk.

Apart from the above discussed critical success factors there are some more critical success factors that have bee identified in several studies some of them are Management style", "Awareness of risk management processes", "Co-operate culture", "Positive human dynamics", "Customer requirements", "strategic planning", "effective use of tools and techniques", "teamwork", and "availability of specialist risk and management consultants". This is very much aligned with what has been used in the research.

4.Methodology

In the literature review section the risk management concepts were covered in respect to the pharmaceutical company. The literature search is based on analysis of findings of other similar studies with a purpose to identify the critical success factors of risk and management practices implementation in pharmaceutical industry. In this section, the research methodology that is chosen to answer the research question will be justified.

Data was collected using self-administered structured questionnaire. Our questionnaire was generated solely for the current research and is not a standard validated instrument. The questionnaire was sent to the subject matter expert of a pharmaceutical company for the feedback before sending it to the subjects of this study. The questionnaire was then sent to the key stakeholders to randomly selected professionals from pharma industries located in Boston area using www.surveymonkey.com on 20th Sept 207 along with an email which provided the invitation and introduction and purpose of the questionnaire.

Majority of the professionals (66.7%) were from the large organization while 33% were from small organization. About 50% of the respondents had 1-5 years of experience in pharmaceutical company and most of them (41.67%) had master's degree.

Table 4. Characteristic of sample by professional background

Position	Frequency	%
Individual contributor	7	58.3%
Team lead	1	8.33%
Senior Manager	1	8.33%
Vice President	1	8.33%
Volunteer	1	8.33%

Administrative	1	8.33%

The background of the respondents is taken into account to support the belief that the respondents were involved in the projects and had knowledge of issues which are related to risk management critical success factors and barriers in deployment. This is being used to enhance internal validity.

The questionnaire was divided into three parts namely demographics, risk awareness and critical success factors of risk assessment and management process. In demographics data was collected to gather information regarding their professional and educational background, number of years of work experience and the size of the company where they work.

The second part was to gather information about their awareness to risk and what kind of risk is important in their projects having binary response will be presented as proportion.

The third part of the questionnaire deals with the 14 critical success factors namely: Support from senior management, Clear and realistic objectives, Good communication, feedback, Skilled/ suitably qualified/ sufficient staff/team, Competent Project manager, Sufficient /well allocated resources, Good leadership, Proven/ familiar technology, Realistic schedule, Risks addressed/ assessed/ managed, Effective monitoring/ control, Adequate budget, Organizational adaptation/ culture/ structure and Training provision. Each factor in the list was measured from a range of 1-5 Likert scale where (1) represents strongly agree, (2) Agree (3) Disagree, (4) represents strongly disagree and (5) Not applicable. The data for this section will be represented in the weighted average.

5.Results

A total of N=20 questionnaires were sent using survey monkey to randomly selected professionals from pharma industries located in Boston area. Out of which 12 questionnaires were completed by the respondents. No missing data is noticed from the questionnaires.

5.1 The Results of General Information

Most of the respondents (66.7%) were from the large organization while 33% were from the small organization. About 59% were individual contributor in their respective organizations and 41% of them were serving as team leads, managers and administrative roles etc. Among them 50% of the respondents had 1-5 years of experience and 50% had more than 5 years of experience in a pharmaceutical company, Comparing the educational qualification 42% had a master's degree, 34% had a doctorate and 24% were graduates and others.

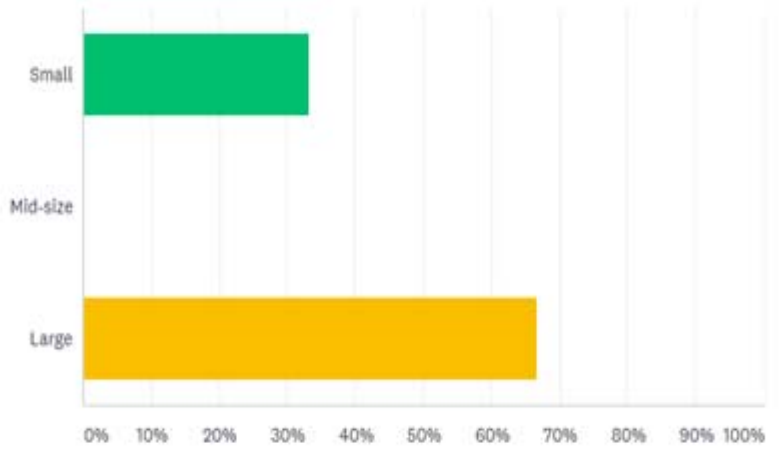

Fig 6 Type of organization of the respondents

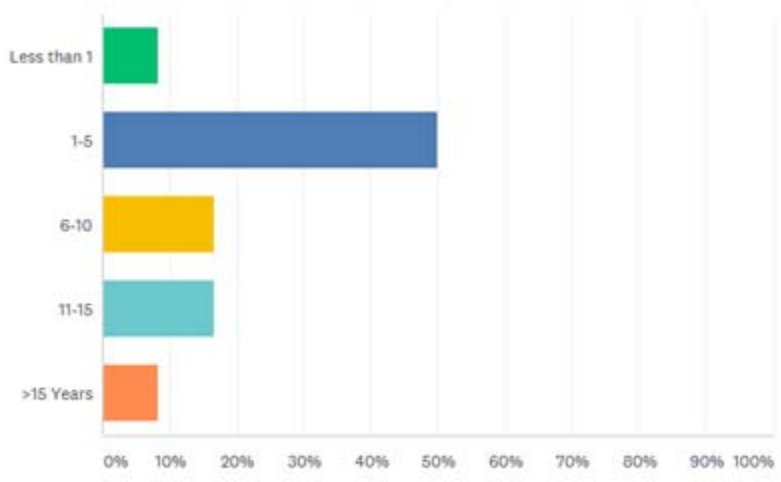

Fig 7. Showing number of years of work experience of the respondents

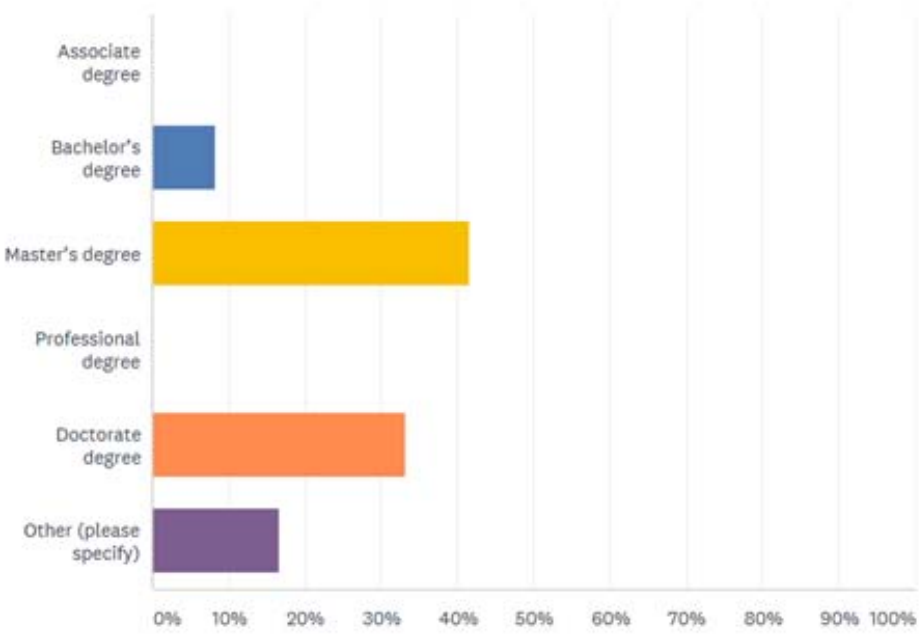

Figure 8 Professional backgrounds of the respondents

Based on the data collected for the study for the risk frequently encountered in pharmaceutical company, it has been found that the regulatory risk (4.17) is more frequently encountered risk in the pharmaceutical industry followed by Relationship risk (4.09), Resource risk (4.00) and operational risk (3.88). Respondents marked the financial risk at the last position (2.33). See Table below

Table 5 Ranking of the risks marked by respondents

Type of risks	Score	Ranking
Financial Risk	2.33	6
Resource Risk	4.00	3
Technical Risk	3.38	5
Operational Risk	3.88	4
Regulatory Risk	4.17	1
Relationship Risk	4.09	2

Fig 9 Ranking of risks based on their importance

5.3 Risk Assessment and awareness

Table 6 indicates that the level of understanding and awareness of the respondents related to risk assessment and management practices. The response as shown in table indicates that 58.33% don't think that they have realistic expectations about their project job, for 50% there are critical skills in the project for which no one is identified and 41.67% people think that that don't have tools in place.

Table 6 Risk Assessment and awareness

S No	Questions	Yes	No
RAQ 1	Is the customer process well understood by anyone in the project's team?	83.33%	16.67%
RAQ 2	Are the tools needed available and in place?	58.33%	41.67%
RAQ 3	Is any part of the product technologically unpredictable?	83.33%	16.67%
RAQ 4	Is the customer process well understood by anyone in the project's team?	91.67%	8.33%
RAQ 5	Is the quantity and quality of the team sufficient to cover the requirements of the project?	83.33%	16.67%
RAQ 6	Does the project require special skills that are provided by third parties?	75.00%	25.00%
RAQ 7	Are there critical skills for which nobody is identified?	50.00%	50.00%
RAQ 8	Are there pressures to staff?	83.33%	16.67%
RAQ 9	Do the people have realistic expectations about their project job?	41.67%	58.33%
RAQ 10	Are the task prerequisites of the team members (e.g., training) satisfied?	83.33%	16.67%
RAQ 11	Is the time frame allocated to the project sufficient for the achievement of the stated goals?	83.33%	16.67%
RAQ 12	Is the customer's process well understood by anyone in the project's team?	75.00%	25.00%
RAQ 13	Is communication with the customer frequent and fluid?	83.33%	16.67%

Checklist taken from http://www.iste.uni-stuttgart.de/fileadmin/user_upload/iste/se/links/links-se/checklists/download/Risk_Assess.html

5.4 Critical Success Factors

Table 3.0 shows overall rankings of critical success factors that are considered necessary for the deployment of the risk assessment and management practices are (1) good leadership(2) Good communication/ feedback (3) Organizational adaptation/ culture/ structure (4) Clear and realistic objectives (5) Familiar technology.

Table 7 Perception and rating critical success factors

S No	**Critical Success factors**	**Weighted Average**	**Ranking**
1	Support from senior management	1.75	8
2	Clear and realistic objectives	1.92	4
3	Good communication/ feedback	2.00	2
4	Skilled/ suitably qualified/ sufficient staff/team	1.58	13
5	Competent Project manager	1.67	11
6	Sufficient /well allocated resources	1.75	9
7	Good leadership	2.00	1
8	Proven/ familiar technology	1.83	5

9	Realistic schedule	1.75	10
10	Risks addressed/ assessed/ managed	1.83	6
11	Effective monitoring/ control	1.67	12
12	Adequate budget	1.82	7
13	Organizational adaptation/ culture/ structure	1.92	3
14	Training provision	1.58	14

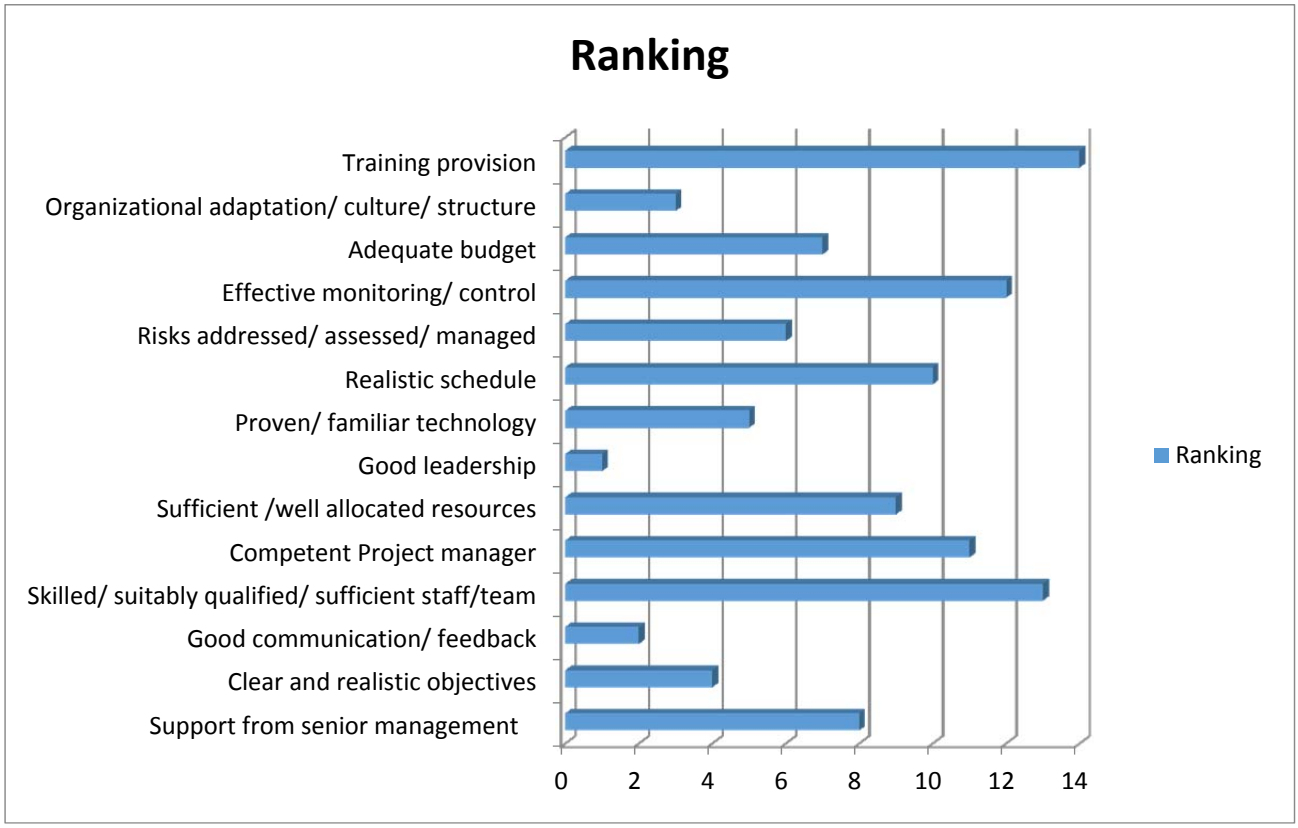

Fig 10 showing the ranking of critical success factors

6. Discussion

The most important risk in pharmaceutical industry is Regulatory risk as indicated in the findings, of our survey questionnaire. According to KPGM Per KPMG 2009 global survey findings it is found that the pharmaceutical Risk management is considered as a C level issue with the shortage of experts in the industry who can handle risks and they usually spend most of their time in controlling regulatory risks which they think is the biggest threat to the company.

Table 1 showing the risks that pose a threat to company's global business. In their survey 67% of the respondents marked regulator risk as number one risk in the pharmaceutical industry. The picture that came out by these findings is that an industry pays attention to what it perceives and in pharmaceutical space they perceive regulatory risk as the most important risk. It is important that companies should do a better job in managing risks that are familiar to them and keeping a watch on the new ones that may come up during the course of project.

Awareness of risk management processes is closely linked to the critical success factors of " effective use of methods and tools" and "availability of specialist risk and management consultants"(Adwoa Agyakwa-Baah and Nicholas, C 2010). In one study conducted Frimpong et al. in 2003 it has been found that the "lack of awareness of risk management processes can inherently lead to poor resource management" which can affect the health of the project.

The top three critical success factors that respondent identified in the survey important for the deployment of the risk assessment and management practices are (1) good leadership (2)

Good communication/ feedback (3) organizational culture. The findings based on the scores are in alignment with other researchers (Tchankova, L 2002 and Agyakwa-Baah, A 2010).

Good leadership: According to project management literature it has been established that the activities, actions and characteristics of a team leader can impact the outcomes of a project significantly. Many researchers like Thite (1999) and Kaissi (2005) have conducted the research showing the impact of project leader on the success of a project. In their research they found that the ability of a project leader to switch effectively between the transactional and transformational leadership styles had a positive impact on the outcomes of a project. Several other studies have also found the performance of team leader as critical for the success of a project (Dvir, 1998; Hyvari, 2006).

Communication: most of the respondents rated communication as a critical factors for the implementation of risk assessment and management practices. It has been recognized as an important area within literature that should be considered by the project leaders. Role of 'open communication with in organization' is always supported by the various scholars (Samson & Terziovski, 1999).

This also aligns with the project management literature that emphasize on the importance open communication between project leaders and members in order to improve the outcomes of the project (Hyvari, 2006; Zimmerer & Yasin, 1998). The development of understanding between management and employee, regularly communicating clear information is important for risk management procedures. Risk can't be managed if there is a lack of communication and support from the upper management.

Organizational culture which is rated as the third most important critical factor by the pharmaceutical professional is very important for risk assessment and management practices.

According to Grabowska and Roberts 1999 risk management is a combination of several cultures which is important for the transfer of knowledge, exchanging ideas and sharing knowledge with one another. Organizational culture as a critical success factor is also supported by the findings of a study conducted by Prapawadee N, R.in 2009.

7. Conclusion

This thesis is presented as a part of MS project management coursework. It is done to identify the critical success factors of risk assessment and management practices in pharmaceutical industry. The study was conducted using a questionnaire survey from randomly selected professionals from Boston, MA who were working in pharmaceutical projects at the time of responding to the questionnaire.

Out of the 14 success factors listed in our questionnaire the top three were found to be good leadership, communication and organizational culture. We also found that the most important risk factor is regulatory risks as perceived by the pharmaceutical professionals.

The significance of our study is mainly to have an insight and applicability of critical risk management success factors in the realm of pharmaceutical industry. Such insight may help in better risk assessment and mitigation practices in this industry.

Our findings underline the importance of good leadership, communication and organizational culture as risk factors and should be taken into consideration during the implementation of risk management process. Also, identification of such factors can help formulate a road map to generate risk minimization action plans at the outset of the project.

As there is dearth of information regarding critical project management risk determinants which are applicable to pharmaceutical project management, the main strength of our study is its application in the pharma space.

Because we set out to do only descriptive statistical assessment based on our questionnaire, we acknowledge the limitations of our study as due to lack of a bigger sample size which could have enabled us to perform grouped and stratified analysis. Also, because of the small sample size collected from one city our study may have limited external validity.

However, we recommend conducting a larger and differently designed study, using a validated instrument that can help answer questions using analytical statistical procedures.

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9. Appendices

Survey Questionnaire

Thank you for taking part in this survey measuring the critical success factors for the implementation of risk assessment and management practices in pharmaceutical industry. This survey should only take 10-15mins to complete. Be assured that all answers you provide will be kept in strict confidentiality. Thank you once again for your time and effort.

I Demographics

1. What is the highest level of education you have completed?

    Associate degree

    Bachelor's degree

    Master's degree

    Professional degree

    Doctorate degree

2. What is your job role?

    Individual Contributor

    Team Lead

    Manager

    Senior Manager

    Management/C-Level

    Administrative

3. How many employees currently work at the location where you work?

    25-49.

50-99.

100-199,

200-300,

More than 300

4. what is the tyoe of your organization ?

Small

Mid Size

Large

5. Number of years of work experience?

Less than 1

1-5

6-10

11-15

>15

II Risk Assement and Awareness Questions

Please choose yes or no options for the questions below:

-Is any technology required that is not well known to the team?	Yes	No
-Are the tools needed available and in place?		
-Is any part of the product technologically unpredictable?		
-Is the customer process well understood by anyone in the		

project's team?		
-Is the quantity and quality of the team sufficient to cover the requirements of the project?		
Does the project require special skills that are provided by third parties?		
-Are there critical skills for which nobody is identified?		
-Are there pressures to staff?		
-Do the people have realistic expectations about their project job?		
-Are the task prerequisites of the team members (e.g., training) satisfied?		
-Is the time frame allocated to the project sufficient for the achievement of the stated goals?		
-Is the customer's process well understood by anyone in the project's team?		
-Is communication with the customer frequent and fluid?		

III which of the following risks do you think are important in your project. Please mark 1, 2, 3, 4, 5, 6, in order of importance (1=most important 6 = least important

Financial risk

Resource risk

Technical risk

Operational risk

Regulatory risk

Relationship risk

IV. Please indicate your level of agreement or disagreement with each of these Critical success factors for successful deployment of risk assessment and management practices.

	Strongly agree	Agree	Disagree	Strongly Disagree	Not Applicable
Support from senior management					
Clear and realistic objectives					
Good communication/ feedback					
Skilled/ suitably qualified/ sufficient staff/team					
Competent Project manager					
Sufficient /well allocated resources					
Good leadership					
Proven/ familiar technology					
Realistic schedule					
Risks addressed/ assessed/ managed					
Effective monitoring/ control					
Adequate budget					

Organizational adaptation/ culture/ structure					
Training provision					

Any other thoughts? ----------